

render it likely to be read and understood by consumers under normal conditions of purchase.

(3) If the warning statement in paragraph (b)(1) of this section is used, the following warning statement must be placed on the package labeling intended to be read by the physician (physician package insert) after the “How supplied” section, which describes special handling and storage conditions on the physician labeling:

NOTE: The indented statement below is required by the Federal government’s Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC’s) [or name of other class I substance, if applicable]:

WARNING: Contains [or Manufactured with, if applicable] *[insert name of substance]*, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

A notice similar to the above WARNING has been placed in the information for the patient [or patient information leaflet, if applicable] of this product under Environmental Protection Agency (EPA) regulations. The patient’s warning states that the patient should consult his or her physician if there are questions about alternatives.

(c) This section does not replace or relieve a person from any requirements imposed under 40 CFR part 82.

[61 FR 20101, May 3, 1996]

§ 801.435 User labeling for latex condoms.

(a) This section applies to the subset of condoms as identified in § 884.5300 of this chapter, and condoms with spermicidal lubricant as identified in § 884.5310 of this chapter, which products are formed from latex films.

(b) Data show that the material integrity of latex condoms degrade over time. To protect the public health and minimize the risk of device failure, latex condoms must bear an expiration date which is supported by testing as described in paragraphs (d) and (h) of this section.

(c) The expiration date, as demonstrated by testing procedures required by paragraphs (d) and (h) of this section, must be displayed prominently and legibly on the primary packaging (i.e., individual package), and higher levels of packaging (e.g., boxes of

condoms), in order to ensure visibility of the expiration date by consumers.

(d) Except as provided under paragraph (f) of this section, the expiration date must be supported by data demonstrating physical and mechanical integrity of the product after three discrete and representative lots of the product have been subjected to each of the following conditions:

(1) Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at 70 °C (plus or minus 2 °C) for 7 days;

(2) Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at a selected temperature between 40 and 50 °C (plus or minus 2 °C) for 90 days; and

(3) Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at a monitored or controlled temperature between 15 and 30 °C for the lifetime of the product (real time storage).

(e) If a product fails the physical and mechanical integrity tests commonly used by industry after the completion of the accelerated storage tests described in paragraphs (d)(1) and (d)(2) of this section, the product expiration date must be demonstrated by real time storage conditions described in paragraph (d)(3) of this section. If all of the products tested after storage at temperatures as described in paragraphs (d)(1) and (d)(2) of this section pass the manufacturer’s physical and mechanical integrity tests, the manufacturer may label the product with an expiration date of up to 5 years from the date of product packaging. If the extrapolated expiration date under paragraphs (d)(1) and (d)(2) of this section is used, the labeled expiration date must be confirmed by physical and mechanical integrity tests performed at the end of the stated expiration period as described in paragraph (d)(3) of this section. If the data from tests following real time storage described in paragraph (d)(3) of this section fails to confirm the extrapolated expiration

date, the manufacturer must, at that time, relabel the product to reflect the actual shelf life.

(f) Products that already have established shelf life data based upon real time storage and testing and have such storage and testing data available for inspection are not required to confirm such data using accelerated and intermediate aging data described in paragraphs (d)(1) and (d)(2) of this section. If, however, such real time expiration dates were based upon testing of products that were not first left unpackaged for the maximum amount of time as described in paragraph (d)(3) of this section, the real time testing must be confirmed by testing products consistent with the requirements of paragraph (d)(3) of this section. This testing shall be initiated no later than the effective date of this regulation. Until the confirmation testing in accordance with paragraph (d)(3) of this section is completed, the product may remain on the market labeled with the expiration date based upon previous real time testing.

(g) If a manufacturer uses testing data from one product to support expiration dating on any variation of that product, the manufacturer must document and provide, upon request, an appropriate justification for the application of the testing data to the variation of the tested product.

(h) If a latex condom contains a spermicide, and the expiration date based on spermicidal stability testing is different from the expiration date based upon latex integrity testing, the product shall bear only the earlier expiration date.

(i) The time period upon which the expiration date is based shall start with the date of packaging.

(j) As provided in part 820 of this chapter, all testing data must be retained in each company's files, and shall be made available upon request for inspection by the Food and Drug Administration.

(k) Any latex condom not labeled with an expiration date as required by paragraph (c) of this section, and initially delivered for introduction into interstate commerce after the effective date of this regulation is misbranded under sections 201(n) and 502(a) and (f)

of Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(n) and 352(a) and (f)).

[62 FR 50501, Sept. 26, 1997]

§ 801.437 User labeling for devices that contain natural rubber.

(a) Data in the Medical Device Reporting System and the scientific literature indicate that some individuals are at risk of severe anaphylactic reactions to natural latex proteins. This labeling regulation is intended to minimize the risk to individuals sensitive to natural latex proteins and protect the public health.

(b) This section applies to all devices composed of or containing, or having packaging or components that are composed of, or contain, natural rubber that contacts humans. The term "natural rubber" includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation.

(1) The term "natural rubber latex" means rubber that is produced by the natural rubber latex process that involves the use of natural latex in a concentrated colloidal suspension. Products are formed from natural rubber latex by dipping, extruding, or coating.

(2) The term "dry natural rubber" means rubber that is produced by the dry natural rubber process that involves the use of coagulated natural latex in the form of dried or milled sheets. Products are formed from dry natural rubber by compression molding, extrusion, or by converting the sheets into a solution for dipping.

(3) The term "contacts humans" means that the natural rubber contained in a device is intended to contact or is likely to contact the user or patient. This includes contact when the device that contains natural rubber is connected to the patient by a liquid path or an enclosed gas path; or the device containing the natural rubber is fully or partially coated with a powder, and such powder may carry natural rubber proteins that may contaminate the environment of the user or patient.

(c) Devices containing natural rubber shall be labeled as set forth in paragraphs (d) through (h) of this section. Each required labeling statement shall be prominently and legibly displayed